K111015

MAY - 6 2011

CardinalHealth

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

STERILE LATEX POWDER-FREE SURGICAL GLOVES WITH HYDROGEL COATING

Applicant: Cardinal Health, Inc.

Address: 1430 Waukegan Road
McGaw Park, IL 60085

Telephone: 847-887-2325

Regulatory Affairs Contact: Tatyana Bogdan, RAC

Date Summary Prepared: February 18, 2011

Product Trade Name: Sterile Latex Powder-Free Surgical Gloves with Hydrogel Coating with Protein Content Label Claim of 50μg/dm^2 or less

Common Name: Surgeon's Gloves

Classification Name: Surgeon's Gloves

Device Description: The proposed device is a sterile latex powder-free surgical glove that is formulated using natural rubber latex. The glove is coated with hydrogel polymer coating.

The glove is manufactured using molds that feature anti-slip finish, independent thumb and mechanically locking cuffs to help prevent cuff roll down. They are offered powder-free and sterile.

Intended Use: A powder-free sterile surgeon's glove is a disposable device made of natural rubber intended to be worn by operating room personnel to protect a surgical wound from contamination.

Predicate Devices: Sterile Latex Powder-Free Surgical Gloves with Nitrile Coating with Protein Content Label Claim of 50 μg/dm^2 or less previously cleared under 510(k) K101811 (product code KGO).

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510(K) SUMMARY OF SAFETY AND EFFECTIVENESS (CONT'D)

Substantial Equivalence:	The proposed device is substantially equivalent to the predicate device identified in this 510(k) summary. Substantial equivalence can be established in regard to intended use, physical properties and characteristics, design and product features. Both gloves are made of natural rubber latex using similar manufacturing process.
Performance Testing:	The glove characteristics are summarized below as compared to ASTM requirements and to the predicate device.
Test:	Result:
Primary Skin Irritation	Gloves are non-irritating.
Guinea Pig Maximization	Gloves do not display any potential for sensitization.
Dimensions	Gloves meet requirements of ASTM D3577.
Physical Characteristics	Gloves meet requirements for rubber surgical gloves per ASTM D3577.
Freedom From Holes	Gloves meet requirements of 21 CFR 800.20 and ASTM D3577.
Powder Residual	Gloves meet powder level requirements for "Powder-Free" designation per ASTM D3577 tested using ASTM standard D6124. Results generated values below 2mg of residual powder per glove.
Protein Content	Gloves have been tested in accordance with ASTM D5712 and yielded the results of less than 50 $\mu g/dm^2$ of total water extractable protein per glove
Clinical Data:	No clinical data is required.
Conclusion:	The Sterile Latex Powder-Free Surgical Gloves with Hydrogel Coating with Protein Content Label Claim of 50$\mu g/dm^2$ or less meet the technological characteristics of ASTM D3577 Standard Specification for Rubber Surgical Gloves and are substantially equivalent to the predicate device identified in this 510(k) summary.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Cardinal Health, Incorporated
C/O Mr. Ned Devine
Responsible Third Party Official
Underwriters Laboratories, Incorporated
333 Pfingsten Road
Northbrook, Illinois 60062

MAY - 6 2011

Re: K111015
Trade/Device Name: Sterile Latex Powder-Free Surgical Gloves with Hydrogel Coating with Protein Content Label Claim of 50 $\mu g/dm^2$ or Less
Regulation Number: 21 CFR 878.4460
Regulation Name: Surgeon's Glove
Regulatory Class: I
Product Code: KGO
Dated: April 21, 2011
Received: April 22, 2011

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111015

Device Name: Sterile Latex Powder-Free Surgical Gloves with Hydrogel Coating with Protein Content Label Claim of 50 µg/dm^2 or less

Indications for Use: A powder-free sterile surgeon's glove is a disposable device made of natural rubber intended to be worn by operating room personnel to protect a surgical wound from contamination.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K111015